Director Clinical Operations

Atsena Therapeutics is a clinical-stage gene therapy company that is leveraging novel AAV vectors designed to overcome the unique hurdles presented by retinal disease to reverse or prevent blindness. Our lead program, ATSN-201, is a gene therapy for X-linked retinoschisis (XLRS), which is currently being evaluated in a Phase 1/2 clinical trial. We are also advancing ATSN-101, a gene therapy for the treatment of *GUCY2D* Leber congenital amaurosis (LCA1) towards a Phase 3 trial. We have additional preclinical programs to treat other forms of inherited retinal disease as well as novel capsid technology suitable for addressing large indications.

At Atsena, we are bringing patients into focus. We are passionate about finding cures for visually impaired and blind individuals and are driven by cutting edge science to ensure we achieve the safest and most effective results.

Position Summary:

Atsena is seeking an experienced and motivated Director of Clinical Operations to lead clinical operations for an upcoming Phase 3 trial. This role involves developing and executing clinical strategies to support trial design, execution, and analysis across all drug development phases. The Director will ensure compliance, quality, and adherence to timelines and budgets.

The ideal candidate has a strong background in clinical operations management, vendor management, quality/compliance, and cross-functional collaboration in biotech or pharma.

Responsibilities:

- Lead and manage clinical operations activities for assigned studies, including:
    - Site feasibility and identification
    - Site start up and close out
    - Site management
    - Recruitment and retention
    - Data management
    - External vendor selection and management including, but not limited to, central laboratories and imaging
    - eTMF oversight and management
    - Inspection Readiness
    - Investigational product management
    - Risk management
- Develop study plans and ensure all studies are executed with high quality within the required timeframe(s) and budget(s)
- Create and implement a cross-functional, comprehensive risk management plan for assigned studies

- Manage the cross functional clinical study team
- Work closely with program management to ensure communication of updates, risks, and issues
- Provide regular and accurate updates regarding the study status to management
- Implement the departmental outsourcing strategy by soliciting, selecting, and overseeing vendors to ensure quality deliverables and adequate resources.
    - Create requests for vendor proposals and evaluate bids
    - Participate in vendor vetting process and vendor selection
    - Initiate vendor setup and manage contracts and change orders
    - Oversee and manage vendor relationships to support study delivery
- Lead cross-functional meetings
- Provide input on departmental budget

Qualifications:

- Minimum 12 years clinical operations experience including at least 4 years managing global clinical studies at a biotech or pharmaceutical company, phase 3 trial management preferred
- Experience managing trials in the US, Japan, EU, and UK
- Preferred experience managing studies in ophthalmology gene therapy
- Prefer experience managing studies in rare disease
- University degree (equal to 4 years of college) in (para-) medical, pharmaceutical, sciences, life-sciences or biosciences
- Thorough understanding of ICH-GCP guidelines and their application in clinical studies

Required Skills:

- Ability to travel (typically < 10%)
- Perseverance mindset with the ability to stick with a task during challenging times
- CRO/Vendor management experience
- Strong leadership skills and the ability to manage multiple projects independently
- Strong organizational, written and oral communication, and tracking skills
- The ability to handle multiple priorities within matrix environment
- Strong problem-solving skills
- Fluent in English (written and spoken)

- Strong computer skills: Word, Excel, PowerPoint, Outlook, Smartsheet